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SHAUGHNESSY NO

REVIEW NO.

EEB REVIEW

DATE IN: 12-26-91 OUT: _____

CASE # : 113858 REREG CASE # : _____
SUBMISSION # : S408670 LIST A, B, C, D
ID # : 010352-00031

DATE OF SUBMISSION 11-29-91

DATE RECEIVED BY EFED 12-19-91

SRRD/RD REQUESTED COMPLETION DATE 02-01-92

EEB ESTIMATED COMPLETION DATE 02-01-92

SRRD/RD **ACTION** CODE/TYPE OF REVIEW 305 - Lbl Rev Amnd

MRID #(S) 421102-01

DP TYPE 001 - Submission Related Data Package

PRODUCT MANAGER, NO. J. Lee (31)

PRODUCT NAME(S) AQUICAR 514 Water Treatment Microbiocide

TYPE PRODUCT F R I N H D Microbiocide

COMPANY NAME Union Carbide

SUBMISSION PURPOSE Review data: mallard acute with

INCLUDE USE(S) Formulation X14

COMMON CHEMICAL NAME Glutaraldehyde plus alkyl dimethyl
benzyl ammonium chloride

REPORT OUTLINE SHEET

CHEMICAL: Aquacar 514 (X14)

TEST MATERIAL: Glutaraldehyde	14.0%
Alkyl dimethyl benzyl ammonium chloride	<u>2.5%</u>
	16.5%

STUDY TYPE: Avian Acute Oral LD₅₀

Test Species: Mallard Duck (Anas platyrhynchos)

STUDY I.D.: beavers, J.M. and Jaber, M. (1984) Acute LD₅₀ Test For Waterfowl and Upland Game Birds; Project No.142-134; Prepared by Wildlife International, Ltd. for Union Carbide Corporation, Terrytown, New York 10591; MRID No. 421102-01.

REVIEW BY:

Name: Curtis E. Laird
Title: Fishery Biologist
Organization: EEB/EFED

Signature:

Date: 1-31-92

Curtis E. Laird

APPROVED BY:

Name: Allen Vaughan
Title: Supervisory Biologist
Organization: EEB/EFED

Signature:

Date:

Allen W. Vaughan

3.9.92

CONCLUSIONS: This study indicates Aquacar X14 is practically nontoxic to mallard duck with an LD₅₀ of 2109 mg/kg. This study does fulfill the requirement in support of registration for an avian acute oral LD₅₀ study.

RECOMMENDATIONS: N/A

BACKGROUND: This study was submitted for EEB review.

DISCUSSION OF INDIVIDUAL TESTS OR STUDIES: N/A

MATERIALS AND METHODS:

a. Test Animals - Test animals were 4 months old mallard duck from Whistling Wings, Hanover, Illinois 61041. Birds were pen reared healthy matured mallard at test initiation.

b. Dosage - Ten birds per dose level; 5 dosage levels plus control (0, 292, 586, 810, 1350 and 2250 mg/kg).

c. Study Design - Birds were tested in a 72 X 90 X 23 cm Beacon battery finishers; temperature was 80 ± 3°F; humidity was 83%; photoperiod was 8L/16D.

d. Statistical Analysis - Binomial test

REPORTED RESULTS: The study author found the acute oral LD₅₀ value to be approximately 2109 mg/kg.

STUDY AUTHOR'S CONCLUSIONS/QA MEASURES: The Quality Assurance Officer stated that " this study was conducted in accordance to the Good Laboratory Practices as published by the U.S. Environmental Protection Agency, Office of Pesticide Programs (Federal Register, Volume 48, No. 230, November 29, 1983, Pages 53946-53969)."

REVIEWER'S DISCUSSION AND INTERPRETATION OF STUDY RESULTS:

A. Test Procedure:

The test procedure followed the recommended EPA protocol of October 1982.

B. Statistical Analysis:

The statistics were verified with the binomial test.

C. Discussion/Result:

Aquacar is practically nontoxic to mallard duck with an LD₅₀ of 2109 mg/kg.

D. Adequacy of Study:

1. Category: Core
2. Rationale: N/A
3. Repairability: N/A

COMPLETION OF ONE LINER FOR STUDY: Yes

CBI APPENDIX:

Laird Aquacur X14 Acute Oral LD50

Mallard Duck

CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB. (PERCENT)
2250	10	6	60.00001	37.69531
1350	10	0	0	9.765625E-02
810	10	0	0	9.765625E-02
486	10	0	0	9.765625E-02
292	10	0	0	9.765625E-02

THE BINOMIAL TEST SHOWS THAT 1350 AND +INFINITY CAN BE USED AS STATISTICALLY SOUND CONSERVATIVE 95 PERCENT CONFIDENCE LIMITS, BECAUSE THE ACTUAL CONFIDENCE LEVEL ASSOCIATED WITH THESE LIMITS IS GREATER THAN 95 PERCENT.

AN APPROXIMATE LC50 FOR THIS SET OF DATA IS 2108.877

WHEN THERE ARE LESS THAN TWO CONCENTRATIONS AT WHICH THE PERCENT DEAD IS BETWEEN 0 AND 100, NEITHER THE MOVING AVERAGE NOR THE PROPORTION TEST CAN GIVE ANY STATISTICALLY SOUND RESULTS.